

## REMARKS

The Office Action of April 10, 2007, has been received and carefully considered. Applicants have amended claims to further refine and define that which Applicants consider to be their invention. In addition, Applicants have cancelled claims 24, 33 and 34, and added new claims 48-50 which are the result of deletion of nested preferential ranges in claims 27 and 29. Applicants have also amended claim 23 by deletion of terms which related to manufacturing, permeability, transparency and use. Applicants have inserted into claim 23, terms relating to specific amounts of plasticizer and copolymer which comprise the catheter. Support for amended claim 23 and its dependent claims can be found in claims 23, 24 and 34 as originally filed, as well as in the specification at page 12, lines 5-30, and page 14, line 18 to page 15, line 14.

Applicants also amended claim 44 to more clearly delineate the process of making the catheter. Applicants deleted terms in claim 44 relating to permeability and transparency, and inserted terms relating to specific amounts of plasticizer and copolymer which comprise the catheter as well as further defined the steps of the process. Support for amended claim 44 can be found on page 13, line 31, to page 14, line 17, and pages 16-17 of the specification. No new matter has been added by these amendments.

### Rejection under 35 U.S.C. §102(b)

The Examiner rejected originally filed claim 23 as anticipated under 35 U.S.C. §102(b), over USP 5,376,085 to Conway et al. ('the '085 patent'). According to the Examiner, the '085 patent teaches an external urinary catheter, having a sheath and a tip portion, and having at least one area that is transparent or permeable. The Examiner has interpreted original claim 23 as a product by process claim because of the term "manufactured by thermoplastic processing". As the limitation of such a claim is only limited to the structure implied by the recited steps, the Examiner alleges that silicone rubber is a thermoplastic substance and therefore is encompassed by the terms of the claim. Applicants respectfully traverse this rejection.

The '085 patent teaches a condom catheter comprised of silicone rubber and an acrylic adhesive in the inner surface. Applicants submit that in view of amended claim 23, the '085 patent does not teach each and every element recited in claim 23. Specifically, claim 23 now recites a urinary catheter comprising 10-60% citrate plasticizer and 40-90% polyamide-polyether block copolymer. Neither of these compositions are silicone rubber, and therefore the '085 patent cannot anticipate claim 23. Withdrawal of this rejection is requested.

Rejections under 35 U.S.C. § 103(a)

The Examiner rejected claims 23-27, 44, 45, and 47 under 35 U.S.C. § 103(a), as being unpatentable over USP 5,554,141 to Wendler ("the '141 patent") in view of EP 1,062,957 to Oda et al. ("EP'957"). The Examiner states that the '141 patent teaches an external urinary catheter having a sheath and tip and having a thermoplastic construction. According to the Examiner, EP'957 teaches a flexible, elastic and transparent device including a catheter made of styrene and ethylene copolymer. The '141 patent allegedly also teaches use of a slip additive, and that the catheter could be made by injection or extrusion molding. The Examiner therefore concludes that it would have been obvious at the time the invention was made, to use the transparent material of EP'957 in the catheter of the '141 patent in order to make it more transparent, because one of ordinary skill would have recognized the benefit of increasing the permeability and transparency of the material. Applicants respectfully traverse this rejection.

Applicants respectfully point out that amended independent claims 23 and 44 both recite urinary catheters comprising at least one thermoplastic elastomer and at least one plasticizer. Furthermore, said combination of elastomer and plasticizer is defined as having a specific range of 10-60% citrate plasticizer and 40-90% polyamide-polyether block copolymer. Neither the '141 patent nor the EP '957 patent teach a polymer suitable for use as a urinary catheter comprising a citrate plasticizer and a polyamide-polyether block copolymer. The '141 patent teaches a styrene based block copolymer, and the EP '957 teaches a combination of aromatic vinyl/ $\alpha$ -olefin block

copolymers. As such, the combination of the '141 patent and the EP'957 patent does not teach or suggest each and every limitation of Applicants' claimed invention, and therefore cannot render Applicants' claims *prima facie* obvious. Applicants respectfully request withdrawal of this rejection.

The Examiner also rejected claims 28-32, 35-38, 40-43, and 46, under 35 U.S.C. § 103(a), as being unpatentable over the '141 patent in view of EP'957, and further in view of Stehr et al. (WO 96/29962) ("the '962 application"). According to the Examiner, neither the '141 patent nor EP'957 disclose a catheter with a tip made separately from the sheath. The Examiner offers the '962 application for teaching a condom catheter having a sheath and tip which are manufactured separately. The Examiner therefore concludes that it would have been obvious at the time the invention was made, to combine the teachings of the '141 patent and EP'957, with the '962 application, in order to make a catheter having different properties in the sheath portion and the tip portion. Applicants traverse this rejection.

As Applicants stated with regard to the previous rejection, neither the '141 patent nor the EP '957 patent teach a polymer suitable for use as a urinary catheter comprising a citrate plasticizer and a polyamide-polyether block copolymer. The '141 patent teaches a styrene based block copolymer, and the EP '957 teaches a combination of aromatic vinyl/ $\alpha$ -olefin block copolymers. This omission is not cured with the addition of the '962 application. The '962 application only teaches condom catheters made of polyurethane. As such, the combination of the '141 patent and the EP'957 patent, in view of the '962 application, does not teach or suggest each and every limitation of Applicants' claimed invention, and therefore cannot render Applicants' claims *prima facie* obvious. Applicants respectfully request withdrawal of this rejection.

Finally, the Examiner rejected claims 33, 34, and 39 under 35 U.S.C. § 103(a), as being unpatentable over the '141 patent in view of EP'957, and further in view of USP 5,417,981 to Endo et al. ("the '981 patent"), USP 4,710,532 to Hull et al. ("the '532 patent"), and USP 6,520,934 to Lee et al. ("the '934 patent"). The Examiner offers the '981 and '532 patents for allegedly teaching the use of ethylene propylene terpolymers and citrate plasticizers respectively. The '934

patent is offered for teaching the use of polyamide-polyethylene block copolymers. The Examiner states that it would have been obvious at the time the invention was made, for one of ordinary skill in the art to use the plasticizers and polymers taught in the '981, '532, and 934 patents, in the catheter of the '141 patent and '962 application, because the materials were known to be suitable for that purpose. Applicants traverse this rejection.

The Examiner rejects claims 33, 34, and 39, because the '981 and '532 patents mention polyamide-polyether block copolymer and citrate plasticizer, respectively. However, neither the '981 nor '532 patents disclose external urinary catheters comprising a tip portion and a sheath portion. These two references only show that polyamide-polyether block copolymers and citrate plasticizers can be used in intravenous, invasive medical devices, such as intravenous and intraarteriel catheters ('981 patent, column 1, lines 11-30) or catheters in general ('532 patent, claim 11). It is not taught or suggested in either reference that such materials would be suitable for urinary medical devices designed to be transparent, and breathable; properties not associated with invasive medical devices. Thus, at the time of filing the application, one of ordinary skill in the art would have no incentive to include a citrate plasticizer and a polyamide-polyether block copolymer, in the material of an external urinary catheter comprising a tip portion and a sheath portion. One might choose the material defined in amended claim 23 as only one of many different polymer possibilities.

Neither the '981 and '532 patents would have taught or suggested to one of ordinary skill in the art the features of amended claim 23, which provide the unexpected properties of the present invention. Moreover, neither the '981 and '532 patents disclose any information that would have motivated one of ordinary skill in the art, at the time of the invention, to combine said materials as a means for improving permeability characteristics of an external urinary catheter. Therefore, Applicants submit that the invention cannot be considered to be *prima facie* obvious, and request withdrawal of this rejection.

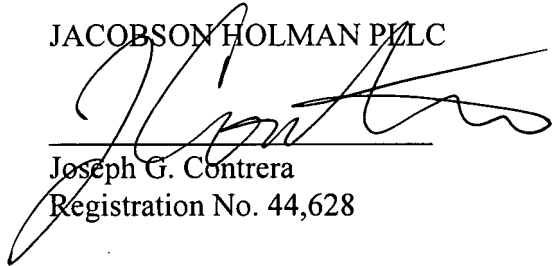
It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner

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believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

JACOBSON HOLMAN PLLC

A handwritten signature in black ink, appearing to read 'J. Contrera', is written over a horizontal line.

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Date: October 3, 2007  
HBJ/JGC/py

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